JENKINS & WILSON, P.A.
PATENT ATTORNEYS
SUITE 1400 UNIVERSITY TOWER
3100 TOWER BOULEVARD
DURHAM, NORTH CAROLINA 27707

TELEPHONE (919) 493-8000
FACSIMILE (919) 419-0383

WEBSITE
JENKINSANDWILSON.COM

RICHARD E. JENKINS
JEFFREY L. WILSON
CHARLES A. TAYLOR, JR.
JENNIFER L. SKORD
DAVID P. GLOEKLER
GREGORY A. HUNT
JOHN A. LAMERDIN, PhD. (PATENT AGENT)

RALEIGH OFFICE
NCSU CENTENNIAL CAMPUS
VENTURE II SUITE 400
920 MAIN CAMPUS DRIVE
RALEIGH, NORTH CAROLINA 27606

TELEPHONE (919) 424-3710
FACSIMILE (919) 424-3711

November 22, 2000

"Express Mail" mailing number.: EK580269058US
Date of Deposit 11-22-00
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Amy J. Martin

Commissioner for Patents
BOX PATENT APPLICATION
Washington, D.C. 20231

Re: U.S. Patent Application for METHOD FOR TREATING HIV
Our File No. 1136/8

Sir:

Please find enclosed the following:

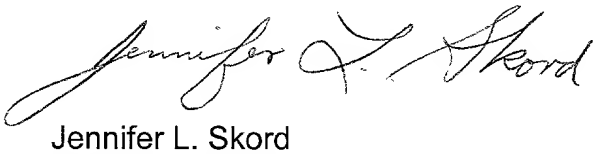
1. A U.S. patent application for METHOD FOR TREATING HIV (22 pages);
2. Executed Declaration (3 pages);
3. Executed Small Entity Statement;
4. Utility Patent Application Transmittal Form (Form PTO/SB/05);
5. Fee Transmittal Form (Form PTO/SB/17) in duplicate;
6. A check in the amount of $364.00 to cover the application filing fee;
7. A return-receipt postcard to be returned to our offices with the U.S. Patent and Trademark Office date stamp thereon; and
8. A Certificate of Express Mail No.: EK580269058US.

Please contact our offices if there are any questions.

Although a check is being submitted, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment associated with the filing of this correspondence to Deposit Account Number **50-0426**.

Respectfully submitted,

JENKINS & WILSON, P.A.



Jennifer L. Skord
Registration No. 30,687

JLS/ajm/sed

Enclosures

11-24-00

A

PTO/SB/05 (08-00)
Approved for use through 10/31/2002. OMB 0651-0032
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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	1136/8
First Inventor	Ralph L. Bass
Title	METHOD FOR TREATING HIV
Express Mail Label No.	EK580269058US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. [X] Fee Transmittal Form (e.g., PTO/SB/17) *(Submit an original and a duplicate for fee processing)*
2. [X] Applicant claims small entity status. See 37 CFR 1.27.
3. [X] Specification [*Total Pages* 22] *(preferred arrangement set forth below)*
   - Descriptive title of the invention
   - Cross Reference to Related Applications
   - Statement Regarding Fed sponsored R & D
   - Reference to sequence listing, a table, or a computer program listing appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
4. [ ] Drawing(s) *(35 U.S.C. 113)* [*Total Sheets*]
5. Oath or Declaration [*Total Pages* 3]
   a. [X] Newly executed (original or copy)
   b. [ ] Copy from a prior application (37 CFR 1.63 (d)) *(for continuation/divisional with Box 17 completed)*
      i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b)
6. [ ] Application Data Sheet. See 37 CFR 1.76

ADDRESS TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231

7. [ ] CD-ROM or CD-R in duplicate, large table or Computer Program *(Appendix)*
8. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   a. [ ] Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. ☐ CD-ROM or CD-R (2 copies); or
      ii. ☐ paper
   c. [ ] Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. [ ] Assignment Papers (cover sheet & document(s))
10. [ ] 37 CFR 3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
11. [ ] English Translation Document *(if applicable)*
12. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
13. [ ] Preliminary Amendment
14. [X] Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
15. [ ] Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
16. [X] Other: ..Executed..Small..Entity ..Statement,...Check..for $364.00

17. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:*

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No _____/_____

Prior application information. *Examiner* _____ *Group / Art Unit* _____

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

18. CORRESPONDENCE ADDRESS

[X] *Customer Number or Bar Code Label* *(Insert Customer No. or Attach bar code label here)* or [ ] *Correspondence address below*

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Address					
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Country		*Telephone*		*Fax*	

Name (Print/Type)	Jennifer L. Skord	*Registration No. (Attorney/Agent)*	30,687
Signature	Jennifer L. Skord	*Date*	November 22, 2000

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PTO/SB/17 (09-00)
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JC968 U.S. PTO 09/721131 11/22/00

FEE TRANSMITTAL for FY 2001

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT ($) 364.00

Complete if Known	
Application Number	
Filing Date	November 22, 2000
First Named Inventor	Ralph L. Bass
Examiner Name	
Group Art Unit	
Attorney Docket No.	1136/8

METHOD OF PAYMENT

1. ☐ The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to.
   Deposit Account Number:
   Deposit Account Name:
   ☐ Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17
   ☐ Applicant claims small entity status. See 37 CFR 1.27
2. ☒ **Payment Enclosed:**
   ☒ Check ☐ Credit card ☐ Money Order ☐ Other

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	710	201	355	Utility filing fee	355
106	320	206	160	Design filing fee	
107	490	207	245	Plant filing fee	
108	710	208	355	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) ($) 355.00

2. EXTRA CLAIM FEES

			Extra Claims		Fee from below		Fee Paid
Total Claims	21	-20** =	1	X	9	=	9
Independent Claims	1	-3** =	0	X	40	=	0
Multiple Dependent						=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	18	203	9	Claims in excess of 20
102	80	202	40	Independent claims in excess of 3
104	270	204	135	Multiple dependent claim, if not paid
109	80	209	40	** Reissue independent claims over original patent
110	18	210	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 9

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for *ex parte* reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	390	216	195	Extension for reply within second month	
117	890	217	445	Extension for reply within third month	
118	1,390	218	695	Extension for reply within fourth month	
128	1,890	228	945	Extension for reply within fifth month	
119	310	219	155	Notice of Appeal	
120	310	220	155	Filing a brief in support of an appeal	
121	270	221	135	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive - unavoidable	
141	1,240	241	620	Petition to revive - unintentional	
142	1,240	242	620	Utility issue fee (or reissue)	
143	440	243	220	Design issue fee	
144	600	244	300	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	240	126	240	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	710	246	355	Filing a submission after final rejection (37 CFR § 1.129(a))	
149	710	249	355	For each additional invention to be examined (37 CFR § 1.129(b))	
179	710	279	355	Request for Continued Examination (RCE)	
169	900	169	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 0

SUBMITTED BY

Complete *(if applicable)*

Name (Print/Type)	Jennifer L. Skord	Registration No. (Attorney/Agent)	30,687	Telephone	(919)493-8000
Signature	Jennifer L. Skord			Date	November 22, 2000

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Practitioner's Docket No. 1136/8 ***PATENT***

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bass, Ralph L
Application No.:
Filed on:
Title: METHOD FOR TREATING HIV

STATEMENT CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27(b)--INDEPENDENT INVENTOR

As a below named inventor, I hereby state that I qualify as an independent inventor, as defined in 37 CFR 1.9(c), for purposes of paying reduced fees to the United States Patent and Trademark Office under Sections 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office, with regard to the invention described in the specification filed herewith, with title as listed above.

I have not assigned, granted, conveyed or licensed, and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who would not qualify as an independent inventor under 37 CFR 1.9(c), if that person had made the invention, or to any concern that would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

No person, concern or organization exists to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention.

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Ralph L Bass

Ralph L Bass Date 11/20/2000

Signature of Inventor

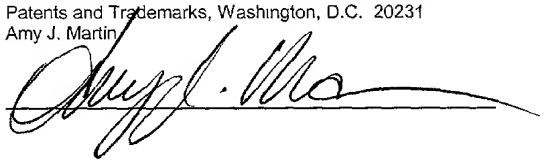
METHOD FOR TREATING HIV

AN APPLICATION FOR

UNITED STATES LETTERS PATENT

By

Ralph L. Bass
Chapel Hill, North Carolina



Description

METHOD FOR TREATING HIV

Technical Field

The present invention relates, in general, to a method for the treatment of HIV, namely Human Immunodeficiency Virus, the causative agent of Acquired Immune Deficiency Syndrome (AIDS). More particularly, the present invention relates to a method for treating a human person infected with HIV comprising administering to the human person a treatment effective amount of sodium chloride.

Background of the Invention

HIV, which causes AIDS, exerts a profound effect on helper/inducer T-cells, devastating the function of the immune system. Presently, a small number of drugs, for instance, zidovudine which is chemically known as 3'-azido-3'-deoxythymidine (AZT) which is a pyrimidine nucleoside analogue and also lamivudine which is chemically known as levo 2',3'-dideoxy,3'-thyacytidine (3TC) which is another pyrimidine nucleoside analogue, are either being used therapeutically or being tested in antiviral chemotherapy for suppression of the AIDS virus. The failure of various antiviral chemotherapies can be attributed partially to a lack of selective toxicity, partially to the development of chronic

resistance to antiviral drugs, and partially to recurrence of infection after drug therapy has terminated.

More specifically, U.S. Patent No. 4,879,277 issued November 7, 1989 to Mitsuya, Broder, and Yarchoan, assignors to the United States of America as represented by the Department of Health and Human Services, discloses a composition of 2',3'-dideoxycytidine, a salt thereof, or an ester thereof in a pharmaceutically acceptable carrier for use in treating HIV infection. The preferred carrier is normal saline (i.e., an aqueous solution of sodium chloride). The composition may be administered intravenously, orally, nasally, rectally, or vaginally.

Also, of interest is U.S. Patent No. 5,213,803 issued May 25, 1993 to Pollock and Docherty, assignors to Northeastern Ohio Universities College of Medicine. This patent discloses a method for killing an envelope virus in vitro causing AIDS and/or Herpes infections by contacting a surface or cavity which is infected with the envelope virus with a formulation of humectant, inorganic monovalent anions, and detergent. The monovalent anions can include sodium bicarbonate, sodium thiocyanate, sodium fluoride, and sodium chloride.

Additionally of background interest, Fisher in "Evaluation of the Health Aspects of Sodium Chloride and Potassium Chloride as Food Ingredients", pp. 1-50 (1979) discusses how much of each of NaCl and KCl is in various commonly consumed foods. Of note, Bajamar Chemical markets (for prescription only sales by pharmacists) powder packets containing 1500 mg of KCl for patients who have a KCl depletion problem, for instance, from taking diuretics.

(All patents mentioned are incorporated by reference.)

Nevertheless, a need still exists for devising other means of treatment for those persons infected with HIV.

Statement of the Invention

Accordingly, the present invention provides a method for the treatment of a human infected with HIV, by administering to the upper gastro-intestinal tract of the human a selected amount of a formulation of sodium chloride. The method comprises (a) administering the sodium chloride formulation to the human's upper gastro-intestinal tract so as to introduce the sodium chloride formulation to the metabolism of the human, and (b) periodically repeating (a) so as to administer a therapeutically effective amount of the sodium chloride formulation to the human's metabolism.

In one embodiment, the sodium chloride formulation is solid, containing sodium chloride, preferably obtained from vacuum granulated sodium chloride that has been compressed into a tablet or that remains as a powder, as further described below. When the sodium chloride formulation is a solid, the solid formulation may contain a majority of sodium chloride, i.e., about 80% to about 100%, more preferably about 95% to about 100% by weight sodium chloride. Nevertheless, amounts less than 80% by weight sodium chloride may desirably be present when potassium ion is also present as discussed below. Furthermore, the solid sodium chloride formulation should be free of a carrier, and/or free of other known medicaments, i.e., AZT, 3TC, and the like, for suppression of the AIDS virus.

In another embodiment, the sodium chloride is in a solution, which formulation is preferably at least 2% by weight sodium chloride. Sodium chloride may be present up to the saturation point in water, i.e., about 32.6% by weight sodium chloride at room temperature (72°F, 22.2°C). Also preferably, the solution formulation is an aqueous solution and should be free of solvents other than water and also free of other known medicaments, i.e., AZT, 3TC, and the like, for suppression of the AIDS virus. Thus, although the solution formulation may consist essentially of water with sodium chloride dissolved in the water, potassium ion also may desirably be present in the solution formulation as discussed below.

In still another embodiment, the sodium chloride formulation includes another ingredient that is the kind of ingredient naturally present in human extracellular fluid and/or human intracellular fluid.

In still another embodiment, the sodium chloride formulation includes another ingredient such as S, P, Zn, Mn, Fe, Cu, Cr, I, Mg, Co, and/or Se.

Accordingly, it is an object of the present invention to provide a treatment for humans infected with HIV.

It is a further object of the present invention that sodium chloride used in the treatment may be orally ingested, and thereby the present invention obviates the drawbacks of intravenous administration.

Some of the objects of the invention having been stated above, others will become evident as the description proceeds, when taken in conjunction with Laboratory Examples as best described below.

Detailed Description of the Invention

More specifically, the inventive method involves administration of a formulation of sodium chloride, the chemical formula of which is NaCl, to treat a human who is infected with HIV, including full-blown AIDS. The administration is to the human's upper gastro-intestinal tract in order to introduce NaCl to the human's metabolism.

In one embodiment, the administration is of a solid formulation of NaCl, such as a tablet or powder, that may be orally administered by being swallowed. In addition to oral administration, contemplated also is administration of a solid formulation of NaCl that is intraoral via the mucous membrane of the mouth (such as sublingual or buccal) or transdermal (such as with a skin patch). A good discussion of intraoral administration can be seen in U.S. Patent No. 4,229,447 issued October 21, 1980 to Porter and in U.S. Patent No. 5,504,086 issued April 2, 1996 to Ellinwood and Gupta. A good discussion of transdermal administration can be seen in U.S. Patent No. 5,016,652 issued May 21, 1991 to Rose and Jarvik.

When the formulation of NaCl is in the form of a solid, the solid formulation may contain between about 55% and about 100% by weight, preferably, about 65% and about 100% by weight, and more preferably, about 75% to about 100% by weight, and even more preferably, about 95% to about 100% by weight, NaCl with only trace amounts, if any, present of other ingredients, for instance, other mineral salts such as magnesium chloride or calcium chloride.

However, other ingredients may be present in the solid formulation of NaCl.

For instance, potassium salts and/or other potassium complexes, may be present. Also, other sodium salts and/or sodium complexes may be present. These particular ingredients are the kinds of ingredients naturally present in human extracellular fluid (plasma fluid or interstitial fluid) and/or in human intracellular fluid. As discussed in Review of Medical Physiology, Ganong, 18th ed., Chapter 1 (The General and Cellular Basis of Medical Physiology), pp. 27-28 (1997), human body fluid naturally contains, in addition to sodium chloride, ingredients such as potassium chloride, potassium carbonate, potassium protein complexes, potassium phosphate, sodium carbonate, sodium protein complexes, and sodium phosphate.

In particular, potassium ion may be present in a Na:K ratio by weight of up to about 1:1. For instance, a solid tablet may contain about 57.5% by weight NaCl and 42.5% by weight KCl, or a solid tablet may contain about 46% by weight NaCl, about 34% by weight KCl, and about 20% by weight various other ingredients such as S, P, Zn, Mn, Fe, Cu, Cr, I, Mg, Co, and/or Se. It is noted that these percents of NaCl and KCl result in a Na:K ratio of about 1:1.

The amount of such other ingredients should be less than about 45%, more preferably less than about 35%, and even more preferably less than about 25% by weight, based on the weight of the sodium chloride. Thus, the amount of sodium chloride would be more than about 55%, more preferably more than about 65%, and even more preferably more than about 75%.

Substantially pure solid NaCl naturally occurs as rock salt, also known as the mineral halite. Halite is translucent when pure, but may be white, yellow, red or blue when trace amounts of other minerals are present.

Also, Eli Lilly of Indianapolis, Indiana markets sodium chloride tablets (1000 mg) for salt replacement by oral administration to humans. Moreover, a NaCl tablet that is about 250 mg (which is a size convenient for swallowing) may be employed for the embodiment of the present invention when the NaCl is a solid formulation.

Furthermore, Morton Salt of Chicago, Illinois markets NaCl. Additionally, provided by Morton Salt to its customers is its NaCl product sold under the trademark PUREX®. PUREX® is a granulated NaCl having a mean average crystal size of 430 microns or 360 microns, depending on whether the product is manufactured at Morton Salt's facility in Rittman, Ohio or Silver Springs, New York, respectively. PUREX® should also be useful in the method of the present invention for when administration of a solid formulation of NaCl comprises administration of powder.

For use in the present invention, the solid formulation of NaCl also may be free of any carriers. For instance, typical pharmaceutically acceptable carriers (such as ethanol, glycerol, stearyl alcohol, polyethylene glycol, propylene glycol, and glycerylmonostearate, often used to place a medicament in solution form or emulsion form for administration) need not be used for the present invention, and preferably, are not used, except as described below vis-a-vis solutions of NaCl such as for administration with a feeding tube.

In an alternative embodiment, the NaCl preferably is in a solution formulation, more preferably an aqueous solution, for administration of NaCl to a human's upper gastro-intestinal tract in order to introduce the NaCl to the human's metabolism. For this solution formulation embodiment, in addition to

oral administration such as by a human swallowing a solution formulation of NaCl by way of the mouth, contemplated also is administration of a solution formulation to the esophagus, stomach, and/or duodenum, such as by gavage, i.e., by way of a feeding tube. Gavage type of administration is useful for when the HIV has progressed in the person to full blown AIDS, and the person can no longer swallow food, medicine, et cetera, by mouth. Nevertheless, to improve palatability when the solution formulation is swallowed, the solution formulation may contain a flavoring. Suitable flavorings may be selected from the group consisting of sugar, coffee, beer, wine, whiskey, fruit juice, milk, soda, mint, and combinations thereof.

Preferably, only water is employed as the solvent in order to place the NaCl in a solution formulation. Thus, although typical pharmaceutical solvents (such as ethanol, glycerol, stearyl alcohol, polyethylene glycol, propylene glycol, and/or glycerylmonostearate, often used to place a medicament in solution form or emulsion form) may be employed in the embodiment of the present invention involving a solution formulation of NaCl, such pharmaceutical solvents are not desired. Hence, the solution formulation should consist essentially of water with NaCl dissolved in the water.

The solution formulation should be at least 2%, more preferably at least 5%, most preferably at least 10%, by weight NaCl, and may be saturated with NaCl. At room temperature, saturation of NaCl in water is about 32.6% by weight NaCl, and at 0°C is about 35.7% by weight NaCl.

As discussed above vis-a-vis the solid formulation of sodium chloride, other ingredients, such as the kinds of ingredients naturally present in human

extracellular fluid (plasma fluid or intestinal fluid) and/or in human intracellular fluid, may be present in addition to sodium chloride in the solution formulation. These are other ingredients such as potassium chloride, potassium carbonate, potassium protein complexes, potassium phosphate, sodium carbonate, sodium protein complexes, and sodium phosphate.

In particular, potassium ion may be, as noted above, present in a Na:K ratio by weight of up to about 1:1. For instance, the non-water components of an aqueous solution formulation of NaCl, based on the weight of the NaCl, may be about 57.5% NaCl and about 42.5% KCl, or may be about 46% NaCl, about 34% KCl, and about 20% various other ingredients such as S, P, Zn, Mn, Fe, Cu, Cr, I, Mg, Co, and/or Se. It is noted that these percents of NaCl and KCl result in a Na:K ratio of about 1:1. Each of the various other ingredients, such as S, P, Zn, Mn, Fe, Cu, Cr, I, Mg, Co, and/or Se, may be individually present in a trace amount up to about 1.8% - 1.9%.

The amount of all such other non-water ingredients should be less than about 45%, more preferably less than about 35%, and even more preferably less than about 25% by weight, based on the weight of the sodium chloride in the solution formulation. Thus, the amount of sodium chloride would be more than about 55%, more preferably more than about 65%, and even more preferably more than about 75%.

Additionally, the solid formulation of NaCl or the solution formulation of NaCl also may be free of any other known medicaments, i.e., AZT, 3TC, and the like, for suppression of the AIDS virus.

For both the solid formulation of NaCl and the solution of NaCl, care should be taken to monitor the amount of potassium present in the patient's blood as potassium is a factor in the clotting of blood and too much can cause the patient to have a problem with hyperkalemia. Nevertheless, when KCl is present, the amount may exceed the 12 to 20 mg average daily intake (see, pp. 38-39 of Fisher, supra), particularly when the patient has a KCl depletion problem (see, Bajamar Chemical's KCl powder packets, supra).

Also, for both the solid formulation of NaCl and the solution formulation of NaCl, the presence of Se, in an amount preferably of at least 120 mcg, is desirable. The reason is that, as is well known, a person with HIV infection often will develop a Se deficiency which is associated with dilated cardiomyopathy. However, the amount of Se should be low enough so that the total daily dosage of Se does not exceed 200 mcg since too much Se is known to cause side effects such as garlic breath, hair loss, and/or nausea.

Administration of the NaCl formulation should be sufficient to provide more than the minimum daily requirement of NaCl according to the National Academy of Sciences, which is a minimum recommendation for Americans of 500 mg/day of sodium (1250 mg/day of NaCl). More preferably, administration of the NaCl formulation should be sufficient to provide more than what the average American chooses to consume (which is 4960 to 6230 mg/day of NaCl according to the U.S. Food and Drug Administration) and should be sufficient to provide more than what the average human of the world's population chooses to consume where salt is readily available (which is 6000 to 11000 mg/day of

NaCl as reported by Bertram in "Sodium Halides, Sodium Chloride", Vol. 22, Kirk-Othmer Encyclopedia of Chemical Technology, 4th Ed., p. 370, 1997).

In view of the amounts described in the paragraph above, the person to whom the NaCl formulation is going to be administered should be monitored for a month or so to determine this person's average daily intake of NaCl, and then, the amount administered should be sufficient to be more. More particularly, the amount administered should be at least 250 mg/day more, more preferably 750 mg/day more, and even more preferably 1250 mg/day more NaCl than the particular person's average daily intake. Hence, administration of the NaCl formulation may be done at least 1 time per day, but may be oftener depending on the severity of the HIV infection in the human and the particular average daily intake of NaCl for that human. Hence, administration may be as often as 5 or 6 times per day, or even more. Typically, for most humans, administration once or twice per day is sufficient. However, regardless of the particular human's average daily intake, administration should be sufficiently more than that average daily intake so that the total daily intake is at least 7500 mg/day, more preferably 9500 mg/day, and even more preferably 11500 mg/day NaCl.

Administration of the NaCl formulation should be repeated (daily, twice daily, etc.) On a regular basis for months or even years, and the HIV infection will have been alleviated and possibly eliminated. In other words, the blood will consistently test negative for the presence of HIV infection. Blood tests, such as ELISA or Western Blot, for the presence of HIV infection in a human patient are well known.

For severe cases, administration of the NaCl formulation should continue for the rest of the human's life. Otherwise, HIV infection may take hold again. Even for other humans, after elimination of the HIV infection, administration may be once per day to maintain the human free of the HIV infection.

Although administration of the NaCl formulation to humans suffering from HIV infection, including humans suffering from AIDS illness and/or humans suffering from related conditions such as AIDS related complex (ARC), under conditions which effectively interrupt or suppress activity of the HIV virus, can be accomplished by one or more of several means of administration as described above, in the preferred embodiment, whatever administrative method is chosen should result in circulating levels of the NaCl within a range of about 0.05 uM to about 1.0 uM. A dosage range of about 0.01-0.25 mg of NaCl/kg of body weight given every 4 hours is considered a virustatic range in most large mammals. In order to achieve this, the preliminary dosage range for oral administration, is slightly broader, being for example, 0.005-0.25 mg of NaCl/kg of body weight given every 4 hours. It is recognized that modifications might need to be made in individual patients to ameliorate or to forestall toxic side effects.

Regardless, the dosage of NaCl must be less than the toxicity measured by a standard called LD_{50}, namely the dosage that is lethal for 50% of the population. Furthermore, the dosage must also be less than the toxicity measured by a standard called TCLo, namely the dosage for oral consumption that is the lowest dosage that has produced toxic effects in humans. As is well

known, the TDLo for NaCl in humans is 12357 mg of NaCl/kg of body weight/day for 23 days of continuous oral consumption.

Laboratory Examples

The following is representative of what would be expected to occur when persons would be treated in accordance with the present invention. All subjects would be first monitored to determine the average daily intake of NaCl for each. Administration to each respective subject always is sufficient to provide at least 250 mg of NaCl per day more than the respective subject's average daily intake.

Example I (Testing with Aqueous NaCl)

Test Subject No. 1. A representative person would be an adult male Caucasian who tests positive in a blood test for HIV infection. Once per day, he would drink 8 ounces of an aqueous solution of 2% by weight NaCl in tap water (about 560 mg of NaCl). This would continue for 5 months, and he should then test negative in a blood test for HIV infection. He stops the treatment, and within 1 month he may test positive in a blood test for HIV infection. Thus, treatment would resume, and in a few months, he should test negative again.

Test Subject No. 2. The method is repeated in the same manner of administration of 2% by weight NaCl in tap water (about 560 mg of NaCl), as with the above-noted male test subject no. 1, but instead with a representative teenaged female person who tests positive in a blood test for HIV infection. Treatment at least once per day would be continued indefinitely and the results

should be that she tests negative in a blood test for HIV infection by about month 5 of the treatment.

Example II

(Testing with solid NaCl)

12 representative persons would be treated by the inventive method, but with a 250 mg tablet of solid NaCl (except certain other ingredients also are incorporated into the tablets, for a total of 250 mg, for test subject nos. 11 and 12, as further discussed below).

No complications result from the use of the NaCl tablets by any of the 12 subjects.

In general, the testing of each of the 12 subjects would be conducted as follows:

A certain number of times per day as indicated, the subject would swallow a NaCl tablet with a 5 ounce glass of tap water.

The administration would be planned to continue for the remainder of the subjects' lives. Depending on the mildness to severity of the HIV condition, generally at some point between 2 months and 5 months, the subjects should intermittently begin to test negative in a blood test administered monthly for HIV infection, and usually within another 2 to 3 months, each subject should consistently test negative. Most subjects would continue with the administration of NaCl tablets to maintain the negative blood test.

12 representative subjects would be as follows:

Test Subjects Nos. 1, 2, and 3. These representative persons would be young adult females each of whom is afflicted with HIV infection. In the past,

each subject would have tried various oral antibiotics for treatment of HIV infection with poor results.

At the time of testing with the NaCl tablet, each subject does not take any medication orally and does not use any medication topically for treatment of HIV infection. Each subject would start once daily administration with the NaCl tablet. After that continues for 6 months, each subject should consistently test negative in a blood test administered monthly for HIV infection. The 3 subjects would continue administration once per day with a tablet of NaCl.

Test Subjects Nos. 4 and 5. Each of these representative persons would be a young adult male with HIV infection that had progressed to the stage of full blown AIDS. In the past, each subject has tried various oral antibiotics, as well as topical antibiotics, with poor results.

At the time of testing with the NaCl tablet, each subject does not take any medication orally and does not use any medication topically. Each subject would start twice daily administration with the NaCl tablets. After that continues for 6 months, each subject may still consistently test positive in a blood test administered monthly for HIV infection due to the full blown AIDS. Thus, administration would be increased to 8 tablets per day for each subject. After 6 more months, each subject should consistently test negative in a blood test administered monthly for HIV infection. The 2 subjects would continue 8 tablets per day administration of the NaCl tablets.

Test Subjects Nos. 6 and 7. These representative persons would be middle-aged adult males with HIV infection. Both would report that when work is stressful, they notice fatigue for long periods of time. In the past, both would

have tried various oral antibiotics for treatment of HIV infection. After 7 months of use once daily of the NaCl tablet, each should consistently test negative in a blood test administered monthly for HIV infection.

Test Subject No. 8. This representative person would be a male senior citizen with HIV infection. After 8 months of using a NaCl tablet once daily, he should consistently test negative in a blood test administered monthly for HIV infection.

Test Subject No. 9. This representative person would be a female senior citizen with HIV infection. After 9 months of swallowing a NaCl tablet once per day, she would still test positive in a blood test administered monthly for HIV infection and show little improvement as compared to other medications previously used for treatment of her HIV infection. However, she would not achieve better results because she would also indicate that she forgets to be consistent in daily use of NaCl.

Test Subject No. 10. This representative person would be a female senior citizen with HIV infection that had progressed to the stage of full blown AIDS. After 10 months of 10 times daily use of the NaCl tablets she should consistently test negative in a blood test administered monthly for HIV infection. She would continue with the 10 tablets of NaCl per day.

Test Subjects Nos. 11 and 12. Testing as per subject no. 10 would be repeated with two females of comparable age and stage of infection.

This time for the first female, the tablets would also contain KCl sufficient to provide a weight ratio in each 250 mg tablet of Na:K of about 1:1, namely about 57.5% NaCl and about 42.5% KCl.

For the second female, the tablets would again contain KCl, but also would contain S, P, Zn, Mn, Fe, Cu, Cr, I, Mg, Co, and Se, namely about 46% NaCl, about 34% KCl, and about 20% of the others, with at least 120 mcg Se per 250 mg tablet. Similar results should be obtained.

It will be understood that various details of the invention may be changed without further departing from the scope of the invention. Furthermore, the foregoing description is for the purpose of illustration only, and not for the purpose of limitation -- the invention being defined by the claims.

CLAIMS

What is claimed is:

1. A method for providing sodium chloride to a human having HIV infection by administering to the upper gastro-intestinal tract of the human a selected amount of a formulation of sodium chloride, said method comprising:

(a) administering the sodium chloride formulation to the human's upper gastro-intestinal tract so as to introduce the sodium chloride formulation to the metabolism of the human; and

(b) periodically repeating (a), so as to administer a therapeutically effective amount of the sodium chloride formulation to the human's metabolism.

2. The method of claim 1, wherein the sodium chloride formulation is free of having other medicaments incorporated therewith for treatment of HIV infection.

3. The method of claim 1, wherein steps (a) and (b) are accomplished at least once per day.

4. The method of claim 1, wherein the amount of the sodium chloride formulation administered is sufficient to provide at least about 250 mg per day more sodium chloride than the human's average daily intake for sodium chloride, as determined after monitoring the human for about 1 month.

5. The method of claim 4, wherein the amount of the sodium chloride formulation administered and the average daily intake for sodium chloride provide at least 7500 mg/day of sodium chloride.

6. The method of claim 1, wherein the sodium chloride formulation is a mixture with a form of potassium in a weight ratio amount of Na:K up to about 1:1.

7. The method of claim 6, wherein the mixture contains up to about 20% by weight of another ingredient selected from the group consisting of S, P, Zn, Mn, Fe, Cu, Cr, I, Mg, Co, Se, and combinations thereof.

8. The method of claim 1, wherein the sodium chloride formulation is free of having other mineral salts incorporated therewith except for trace amounts thereof.

9. The method of claim 1, wherein the sodium chloride formulation is in a form selected from the group consisting of a solid formulation of sodium chloride and a solution formulation of sodium chloride.

10. The method of claim 9, wherein the solid formulation contains from about 55% to about 100% of sodium chloride.

11. The method of claim 10, wherein the solid formulation contains from about 75% to about 100% by weight sodium chloride.

12. The method of claim 9, wherein the solid formulation of sodium chloride is free of having a carrier incorporated therewith.

13. The method of claim 9, wherein the solid formulation of sodium chloride is selected from the group consisting of a tablet, a powder, and a combination thereof.

14. The method of claim 9, wherein administration of the solid formulation of sodium chloride is administration selected from the group consisting of oral, sublingual, buccal, transdermal, and a combination thereof.

15. The method of claim 9, wherein the solution formulation of sodium chloride contains at least about 2% by weight sodium chloride.

16. The method according to claim 9, wherein the solution formulation of sodium chloride is aqueous.

17. The method according to claim 9, further including a flavoring in the solution formulation of sodium chloride to improve palatability.

18. The method according to claim 17, wherein the flavoring is selected from the group consisting of sugar, coffee, beer, wine, whiskey, fruit juice, milk, soda, mint, and combinations thereof.

19. The method of claim 9, wherein administration of the solution formulation of sodium chloride is administration selected from the group consisting of oral, gavage, and a combination thereof.

20. The method according to claim 1, wherein the administration to the upper gastro-intestinal tract is by way of a portion of the upper gastro-intestinal tract selected from the group consisting of a mouth, an esophagus, a stomach, a duodenum, and a combination thereof.

21. The method according to claim1, further including a minor amount of another ingredient selected from the group consisting of potassium chloride, potassium carbonate, potassium protein complexes, potassium phosphate, sodium carbonate, sodium protein complexes, sodium phosphate, and combinations thereof, wherein the total minor amount of said other ingredients is less than about 45% by weight, based on the weight of the sodium chloride.

Abstract of the Disclosure

A method for the treatment of humans having HIV infection. Sodium chloride in a solid formulation or sodium chloride a solution formulation is used.

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[X] Declaration Submitted with Initial Filing **OR** [ ] Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	1136/8
First Named Inventor	Bass, Ralph L
COMPLETE IF KNOWN	
Application Number	
Filing Date	
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METHOD FOR TREATING HIV

(Title of the Invention)

the specification of which

[X] is attached hereto

OR

[ ] was filed on (MM/DD/YYYY) [ ] as United States Application Number or PCT International Application Number [ ] and was amended on (MM/DD/YYYY) [ ] (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

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Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
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Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Ralph L	Bass

Inventor's Signature	[signature]					Date	
Residence: City	Chapel Hill	State	NC	Country	U.S.A.	Citizenship	U.S.A.
Post Office Address	3708 Sweeten Creek Road						
Post Office Address							
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Name	Registration Number	Name	Registration Number
John A. Lamerdin	44,858		

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